

40810-18

5-8-2003
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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MAY 08 2003

Elizabeth Brown
Agent for Ciba Specialty Chemicals Corporation
c/o ChemReg International
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192

Subject: Irgaguard B 5000
EPA Reg. No. 40810-18
Your Amendment Dated 11/18/02, and Re-Submission Dated 5/1/03

The amendment and re-submission referred to above, submitted in connection with registration under section 3 (c) (7) (A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add certain indirect food contact uses, and which provided a migration study (MRID 45803302), a toxicology review (MRID 45803301), and a copy of the FDA food contact approval notification #193, is acceptable under the following requirements and conditions.

1. The following outstanding indirect food contact data for silver and zinc must be satisfied by 6/8/05. The Agency will provide guidance to you soon on the correct test substance to use for satisfying these data requirements. All tier one and other food data requirements for the actives have been satisfied by the revised matrix dated 4/30/03.

870.3150 Subchronic oral toxicity (90 day feeding, non-rodent)
870.3800 Two generation reproduction and fertility effects, rat

2. All the indirect food uses listed on the proposed draft label dated 4/30/03 have a time-limited approval which automatically expires on 6/8/05. The basis for granting interim approval now with outstanding data, is that the product formula has FDA approval for indirect food contact use only when first incorporated into polymers, as stated in the FDA Food Contact Notification #193 (www.cfsan.fda.gov/). If these outstanding data are not fully satisfied by 6/8/05, the Agency will require you to delete them from the label.

3. After you satisfy the outstanding data listed above, an aggregate risk assessment will be conducted for the new indirect food contact uses. If this risk assessment is not found acceptable, the Agency may require you to delete all or certain uses.

4. The submitted migration study was not reviewed because the aggregate risk assessment for

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these new uses could not be completed without the outstanding data. Therefore, your response to this letter should request that the migration study be reviewed in conjunction with satisfying the outstanding data.

5. You must submit/cite all data required for registration and/or re-registration of your product under FIFRA section 3 (c) (5) and section 4 when the Agency requires all registrants of similar products to submit such data.

6. All subsequent amendments that are approved for this product will also be time-limited to expire on 6/8/05.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the approved time-limited label is enclosed for your records.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443.

Sincerely,

Tony Kish for

Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

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